K043056

DEC 22 2004

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material
Common Name:	Staple Line Reinforcement Material
Classification Name:	Surgical Mesh
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery Devices
Establishment Registration Number:	2025240
Contact Person:	Brandon Hansen Regulatory Affairs Medical Products Division WL Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-3784 Facsimile: (928) 864-4144 E-mail: *bhansen@wlgore.com*

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material consists of a bioabsorbable membrane formed into a sleeve with use of a polyester braided suture pullcord. The bioabsorbable material is comprised of a microporous structure of synthetic bioabsorbable glycolide and trimethylene carbonate copolymer. The GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material is to be used with surgical stapling devices.

The GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material is supplied in sterile, foil film laminate pouches. Pouches contain the necessary material for the cartridge jaw and the anvil jaw of the surgical stapler. Tyvek® inserts facilitate placement of the reinforcement material onto the stapler jaws.

Indication for Use

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures.

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material is also intended to be used for reinforcement of suture-lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Substantially Equivalent Devices

In WL Gore & Associates' opinion, the GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction, and labeling.

- SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material (WL Gore & Associates, Inc., Flagstaff, AZ) – K030782 and K032865
- GORE-TEX® Vascular Graft (WL Gore & Associates, Flagstaff, AZ) – K991683

Summary of Studies

In vivo studies support the modification to the "Indication for Use" of the GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material for reinforcement of staple lines during hysterectomy, liver resection, bladder reconstruction, bronchial, cardiac, esophagus, pancreas, and spleen surgical procedures.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the WL Gore & Associates, Inc. GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Mr. Brandon Hansen
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, Arizona 86002

Re: K043056
Trade/Device Name: Gore Seamguard Bioresorbable Staple Line Reinforcement Material
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: November 4, 2004
Received: November 5, 2004

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043056

Indications for Use

510(k) Number (if known): K043056

Device Name: Gore Seamgaurd Bioresorbable Staple Line Reinforce ment Material

Indications For Use:

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures.

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Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043056

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)